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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,553	11/28/2001	Li Wang	P-4825.00	5897

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EXAMINER	
DROESCH, KRISTEN L	

ART UNIT	PAPER NUMBER
3762	

DATE MAILED: 06/17/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/998,553	Applicant(s) WANG ET AL.	
	Examiner Kristen L Droesch	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(e). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/21/03 (IDS)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 January 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3,4*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Schroeppel et al. (5,749,900).

3. With respect to claims 1, and 16, Schroeppel et al. shows a method for and sensing means for sensing cardiac activity of a patient; first detector means (252) for differentiating an arrhythmia in response to differences in ventricular rate variabilities in the sensed cardiac activity and outputting a signal in response to the differentiated arrhythmias; trigger means (258) receiving the signal from the detector means and initiating storage of the sensed cardiac activity (Fig. 9, Col. 12, lines 6-34).

Claim Rejections - 35 USC § 103

4. Claims 1-5, 16-17, 20-21 are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (5,259,621) in view of Wilson et al. (5,908,392).

With respect to claims 1, and 16, Bardy et al. shows a method for and sensing means for sensing cardiac activity of a patient; first detector means for differentiating an arrhythmia in response to differences in ventricular rate variabilities in the sensed cardiac activity and outputting a signal in response to the differentiated arrhythmias (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68). Although Bardy et al. fails to teach trigger means for receiving the signal

from the detector means and initiating storage of the sensed cardiac activity, attention is directed to Wilson et al. (5,908,392) which teaches trigger means for receiving the signal from the detector means and initiating storage of the sensed cardiac activity in order to provide the medical practitioner with the most important form of inter-visit medical data recorded during a cardiac episode (Col. 2, lines 9-63). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy et al. to provide trigger means for receiving the signal from the detector means and initiating storage of the sensed cardiac activity as Wilson et al. teaches in order to provide the medical practitioner with the most important form of inter-visit medical data recorded during a cardiac episode.

Regarding claims 2-3, 17, and 20, Bardy et al. shows first detector means that determine a number of beat-to-beat variations that are greater than a predetermined beat-to-beat variation and identifies the cardiac activity in response to the number and determines whether the number of beat-to-beat variations that are greater than a predetermined beat-to-beat variation is greater than or equal to a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68).

With respect to claims 4, and 21, Bardy et al. shows the cardiac activity is determined to be an irregular rhythm (fibrillation) in response to the number of beat-to-beat variations that are greater than the predetermined beat-to-beat variation being greater than or equal to a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68).

Regarding claims 5, and 21, Bardy et al. shows the cardiac activity is determined to be a regular rhythm (tachycardia not fibrillation) in response to the number of beat-to-beat variations

that are greater than the predetermined beat-to-beat variation being less than a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, lines 49-68).

5. Claims 6-8, and 18-19 are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (5,259,621) in view of Wilson et al. (5,908,392) as applied to claims 1 and 16, and further in view or Padmanabhan (WO00/51680). Bardy et al. and Wilson et al. are as explained before. Bardy et al. further a second detector means for detecting a QRS interval corresponding to the cardiac activity to compute a first predetermined number of R-R intervals, and wherein the first detector means computes an average RR interval corresponding to a predetermined number of the first predetermined number of RR intervals, computes beat-to-beat variation differences between the first predetermined number of RR intervals, and compares the beat-to-beat variation differences to a predetermined beat-to-beat variation corresponding to the average RR interval (Col. 10, lines 31-41; Col. 15, lines 40-68). Although Bardy et al. and Wilson et al. fail to teach utilizing median RR intervals; attention is directed to Padmanabhan, which teaches a similar device and method for determining heart rate variability. Padmanabhan teaches that the process for calculating median interval values is more simplified compared to the process of calculating mean values of measured intervals and reduces storage requirements (Page 3, lines 3-6; Page 7, lines 15-19). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy et al. and Wilson to utilize a median RR intervals as Padmanabhan teaches in order to simplify the process for calculating median interval values compared to the process of calculating mean values of measured intervals and to reduce storage requirements.

Regarding claims 7 and 19, Bardy et al. further shows the beat-to-beat variation differences are calculated by taking the difference of the absolute value of RR(n)-RR(n-1), wherein RR(n) and RR(n-1) are consecutive RR intervals of the first predetermined number of RR intervals (Col. 9, lines 56-Col. 10, line 8).

With respect to claim 8, Bardy et al. shows first detector means that determine a number of beat-to-beat variations that are greater than a predetermined beat-to-beat variation and identifies the cardiac activity in response to the number and determines whether the number of beat-to-beat variations that are greater than a predetermined beat-to-beat variation is greater than or equal to a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68).

Regarding claim 9, Bardy et al. shows the cardiac activity is determined to be an irregular rhythm (fibrillation) in response to the number of beat-to-beat variations that are greater than the predetermined beat-to-beat variation being greater than or equal to a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68).

6. Claims 11–14, and 23 are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (5,259,621) in view of Padmanabhan (WO00/51680). Bardy et al. shows a method for discriminating heart rhythms in an implantable medical device comprising the steps of receiving a QRS interval corresponding to the heart rhythm and computing a first predetermined number of RR intervals from the received QRS intervals; computing a average RR interval corresponding to a predetermined number of the first predetermined number of RR intervals; determining a predetermined beat-to-beat variation corresponding to the computed median RR interval;

computing beat-to-beat variation differences between the first predetermined number of RR intervals; comparing the beat-to-beat variation differences to the predetermined beat-to-beat variation to determine variations in the beat-to-beat variation differences; and identifying the heart rhythm in response to the variations in the beat-to-beat variation differences or determining whether the computed beat-to-beat variation differences are greater than the predetermined beat-to-beat variation; and determining whether a number of the computed beat-to-beat variation differences that are greater than the predetermined beat-to-beat variation is greater than the predetermined count; identifying the heart rhythm as an irregular rhythm in response to the number being greater than or equal to the predetermined count; and identifying the heart rhythm as a regular rhythm in response to the number being less than the predetermined count. (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68). Although Bardy et al. and Wilson et al. fail to teach utilizing a median RR intervals, attention is directed to Padmanabhan, which teaches a similar device and method for determining heart rate variability. Padmanabhan teaches that the process for calculating median interval values is more simplified compared to the process of calculating mean values of measured intervals and reduces storage requirements (Page 3, lines 3-6; Page 7, lines 15-19). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Bardy et al. and Wilson to utilize a median RR intervals as Padmanabhan teaches in order to simplify the process for calculating median interval values compared to the process of calculating mean values of measured intervals and to reduce storage requirements.

Regarding claim 12, Bardy et al. further shows the beat-to-beat variation differences are calculated by taking the difference of the absolute value of RR(n)-RR(n-1), wherein RR(n) and

RR(n-1) are consecutive RR intervals of the first predetermined number of RR intervals (Col. 9, lines 56-Col. 10, line 8).

With respect to claim 13, Bardy et al. shows the cardiac activity is determined to be an irregular rhythm (fibrillation) in response to the number of beat-to-beat variations that are greater than the predetermined beat-to-beat variation being greater than or equal to a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, line 49-68).

Regarding claim 14, Bardy et al. shows the cardiac activity is determined to be a regular rhythm (tachycardia not fibrillation) in response to the number of beat-to-beat variations that are greater than the predetermined beat-to-beat variation being less than a predetermined count associated with the predetermined beat-to-beat variation (Col. 9, lines 56-Col. 10, line 8; Col. 15, lines 49-68).

7. Claims 10, and 22 are are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (5,259,621) in view of Wilson et al. (5,908,392), and Padmanabhan (WO00/51680) as applied to claims 9 and 21, and further in view or Olson et al. (5,855,593). Bardy et al., Wilson et al., and Padmanabhan are explained as before. Although Bardy et al., Wilson et al., and Padmanabhan fail to teach the irregular rhythm corresponds to atrial fibrillation, attention is directed to Olson et al. which teaches it is known to measure ventricular rate variability to distinguish amongst different arrhythmias including atrial fibrillation. Therefore, it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to correlate the irregular rhythm to atrial fibrillation since it is known in the art to

distinguish amongst different arrhythmias including atrial fibrillation based on ventricular rate variabilities.

8. Claims 15, and 24 are rejected under 35 U.S.C. 103(a) as being obvious over Bardy et al. (5,259,621) in view of Padmanabhan (WO00/51680) as applied to claims 14 and 23, and further in view or Olson et al. (5,855,593). Bardy et al., and Padmanabhan are explained as before. Bardy et al further shows the beat-to-beat variation differences are calculated by taking the difference of the absolute value of RR(n)-RR(n-1), wherein RR(n) and RR(n-1) are consecutive RR intervals of the first predetermined number of RR intervals (Col. 9, lines 56-Col. 10, line 8). Although Bardy et al., and Padmanabhan fail to teach the irregular rhythm corresponds to atrial fibrillation, attention is directed to Olson et al. which teaches it is known to measure ventricular rate variability to distinguish amongst different arrhythmias including atrial fibrillation. Therefore, it would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to correlate the irregular rhythm to atrial fibrillation since it is known in the art to distinguish amongst different arrhythmias including atrial fibrillation based on ventricular rate variabilities.

Conclusion

9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Corbucci (5,645,570) shows a device thatcounts the number of RR intervals that vary by more than 6.25% from the preceding RR interval. Krig et al. (6,317,632) determines ventricular rate stability based on a comparison of the average variance to a threshold. Stadler (6,567,691) calculates an expected range of RR intervals based on a trimmed mean and a metric of RR variability derived over a preceding series of RR intervals in order to classify arrhythmias.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen L Droesch whose telephone number is 703-605-1185. The examiner can normally be reached on M-F, 10:00 am - 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angie Sykes can be reached on 703-308-5181. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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